REMARKS:

Upon entry of this Amendment, Claims 1, 2, 4, and 6 to 13 will be pending. Claims 3 and 5 are hereby canceled without prejudice to or disclaimer of the underlying subject matter. Claims 1 and 4 are amended. Claims 9 to 13 are newly added. Support for the amended claims and new claims may be found throughout the specification. *See, for example,* page 8, line 25 to page 9, line 11; page 14, lines 21-26; page 15, line 26 to page 17, line 26; page 22, line 8 to page 23, line 13; in the original claims and the Sequence Listing. No new matter is added by way of these amendments.

I. Status of Prosecution

An appeal brief was filed on August 8, 2007. The Examiner indicates in the Office Action, however, that "[I]n view of the appeal brief filed on 8/8/2007, PROSECUTION IS HEREBY REOPENED." *Office Action* at page 2. Moreover, the Examiner indicates that "[n]ew grounds of rejection are set forth" in the Office Action. *Id.* The Examiner also requires the Applicant to either: "(1) file a reply under 37 CFR 1.111...; or (2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37." *Id.* Applicants acknowledge that prosecution has been reopened in the present Office Action and Applicants submit the instant response under 37 CFR 1.111.

II. Claim Rejections under 35 U.S.C. § 101:

The Examiner rejected claims 1 to 8 under 35 U.S.C. § 101, because the claimed invention allegedly "is not supported by either a specific or substantial asserted utility or a well established utility." *Office Action* at page 3. Applicants respectfully disagree with the rejection.

In addition to the asserted utilities in the specification, Applicants have demonstrated the utility of SEQ ID NO: 11 by conducting a BLASTN analysis. The specification as filed discloses that a BLASTN analysis is a well-known and conventional technique that can be used to obtain information on nucleic acid sequences. *Specification* page 5, line 19 to line 28. The results of a BLASTN analysis of SEQ ID NO: 11 show that SEQ ID NO: 11 has 99 percent identity to 66% of a storage protein-encoding sequence obtained from *Triticum aestivum*. *See*, Applicants' Amendment under 37 C.F.R. § 1.111 filed on November 3, 2006 ("Amendment") at page 6. Applicants respectfully submit that the results of the BLASTN analysis demonstrate that SEQ ID NO: 11 has utilities specific to it and not generally applicable to any nucleic acid.

The Examiner alleges that in Applicants' Amendment, no alignment is provided nor does the response provide what database this alignment is obtained from, nor which sequence from Kawaura this corresponds to. *Office Action* at page 8. Applicants respectfully disagree with the Examiner's assertion, and submit that Applicants submitted the statistical summary of a specific alignment between a known wheat storage protein-encoding sequence (Wh Triticum aestivum cDNA clone wh12e03 3') and SEQ ID NO: 11 produced by a BLASTN analysis through the National Center of Biotechnology Information (NCBI) website. *See Amendment* at page 6.

In *In re Fisher*, the Federal Circuit reiterated that the "basic *quid pro quo* contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived from

the public from an invention with *substantial utility*." *In re Fisher*, 421 F.3d 1365, 1371 (Fed. Cir. 2005) (citing *Brenner v. Manson*, 383 U.S. at 534-35, 1966) (emphasis in original). The Court noted that since "*Brenner* our predecessor court, the Court of Customs and Patent Appeals, and this court have required a claimed invention to have a specific and substantial utility to satisfy § 101." *Id.* Furthermore, an invention need only provide one identifiable benefit to satisfy 35 U.S.C. § 101. *See Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 958 (Fed. Cir. 1983) ("when a properly claimed invention meets at least one stated objective, utility under section 101 is clearly shown").

Although the Supreme Court has not defined the meaning of the terms "specific" and "substantial", the Federal Circuit has identified a framework for the kind of disclosure an application could contain to establish a specific and substantial utility. *In re Fisher*, 421 F.3d at 1371. First, the Court indicated that to provide a substantial utility, the specification should disclose a utility such that "one skilled in the art can use a claimed discovery in a manner which provides some *immediate benefit to the public*." *Id.* (emphasis in original). Second, a specific utility can be disclosed by discussing "a use which is not so vague as to be meaningless," that is that the claimed invention "can be used to provide a well-defined and particular benefit to the public." *Id.*

Claims 1, 2, 4 and 6 to 8 are directed generally to, *inter alia,* substantially purified nucleic acid molecules comprising the nucleic acid sequence of SEQ ID NO: 11 or the complement thereof. Applicants have provided a specific, substantial, and credible utility for SEQ ID NO: 11. For example, the specification clearly discloses that SEQ ID NO: 11 encodes a wheat protein or fragment thereof. *Specification* at page 18, lines 20 to 23. Further, in

Applicants' Amendment filed on November 3, 2006, Applicants submitted the results of a BLASTN analysis reflecting that SEQ ID NO: 11 translates to a wheat storage-protein (E-value = 6E-141, where a "high" BLAST match is considered as having an E-value as less than 1E-30). *See* Amendment at page 6.

The specification discloses, for example, that the nucleic acid molecule encodes a wheat protein, or fragment thereof, exhibiting a BLAST score of greater than 120, preferably between about 1450 and about 120, and even more preferably greater than 1450 with its homolog. *See Specification* at page 18, lines 20 to 23. Indeed, nucleic acid molecules that exhibit high homology to nucleic acid molecules encoding a wheat protein are one of the preferred embodiments of the invention. *Id.* at page 18, lines 8 to 19. Applicants have demonstrated this homology by submitting the results of the BLASTN analysis referred to above.

In other words, SEQ ID NO: 11 (as one example) has utilities specific to it and not generally applicable to any nucleic acid. For instance, SEQ ID NO: 11 can be used to isolate genes, map genes, and determine gene function associated with protein storage. In addition, the specification also discloses that the claimed nucleic acid molecules can be used to monitor the expression of such a protein, for example in a plant cell. *See, e.g., Specification* at page 45, lines 25 to 28. The specification also discloses that such sequences can be used to transform plants to modify the expression of a storage-protein, for example, in a plant cell. *See, e.g., Specification* at page 53, lines 2 to 22. These utilities are credible, substantial, and well-established; they are neither vague nor impractical. The Applicants need only establish a single utility to satisfy 35 U.S.C. § 101, and have done so in the present case. Therefore, one of ordinary skill in the art

would recognize that the claimed nucleic acid molecules have utility. Furthermore, these utilities are immediately apparent without further research.

The Examiner argues that "it is not clear or apparent what reasonable correlation is determined from 99% identity over only a portion of SEQ ID NO: 11 (66%) with a [known protein-encoding] sequence..." *Office Action* at page 10. However, the Examiner has provided no evidence that one of ordinary skill in the art would determine that such a correlation would not *reasonably* support the utilities disclosed by Applicants. To the contrary, Applicants respectfully submit that by showing that the claimed SEQ ID NO: 11 is reasonably correlated with a known protein-encoding sequence, the utility of SEQ ID NO: 11 is specific, substantial, and credible.

The utility of SEQ ID NO: 11 is *specific* because it is specific to SEQ ID NO: 11 and not generally to any nucleic acid sequence. In other words, SEQ ID NO: 11, and not just any general nucleic acid sequence, shares 99 percent identity over 66% of the length of a storage protein-encoding sequence obtained from *Triticum aestivum*. This utility is *substantial* and *credible* because the nucleic acid molecules of the present invention can be used to isolate genes, map genes, and determine gene function associated with protein storage. Storage proteins (in plants) are important for human nutrition. Furthermore, there exists an interest in the production of mutants with an increased protein content or an increased amount of essential amino acids. *See, e.g.*, http://www.biologie.uni-hamburg.de/b-online/e17/17i.htm (accessed on June 4, 2007) (providing an introduction to storage proteins in plants). These utilities are substantial and credible, not vague or impractical.

Therefore, Applicants respectfully submit that they have satisfied the utility test set forth in *In re Fisher*, *i.e.*, that the utilities of SEQ ID NO: 11 are specific, substantial, credible, and well-established. SEQ ID NO: 11 is reasonably (*i.e.*, E-value = 6E-141) correlated with a nucleic acid sequence encoding a wheat storage-protein, therefore, the claimed invention has specific, substantial, credible, and well-established utilities.

Finally, Applicants respectfully remind the Examiner that the utilities asserted in the specification must be accepted as factually sound unless the Patent Office cites information that undermines the credibility of the assertion. *In re Brana*, 51 F.3d 1560, 1567, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995). As the Examiner is aware, "a 'rigorous correlation' need not be shown in order to establish practical utility; 'reasonable correlation' is sufficient." *See, Fujikawa v. Wattanasin*, 93 F.3d 1559, 1565, 39 U.S.P.Q.2d 1895, 1900 (Fed. Cir. 1996), emphasis added. "An Applicant can establish this reasonable correlation by relying on statistically relevant data documenting the activity of the compound or composition, arguments or reasoning, documentary evidence, or any combination thereof." M.P.E.P. § 2107.03, at page 2100-43. The confirmatory BLASTN analysis (discussed below) confirms what Applicants have previously submitted, *i.e.*, that a 99 percent identity over 66 percent of the length of a storage protein-encoding sequence obtained from *Triticum aestivum* is a reasonable correlation to support the specific, substantial and credible utilities asserted for SEQ ID NO: 11.

The Examiner has provided no support for the assertion that the utilities of SEQ ID NO: 11 are not specific, substantial, and credible. Rather, the Examiner's position is that "the utility is not specific because it is a property of all wheat plant nucleic acids..." *Office Action* at page 4. The Examiner's analysis is not in accordance with the ruling of *In re Fisher*.

While it is true that any nucleic acid sequence can be used for a BLASTN search to obtain sequences that share homology with it, a random or general nucleic acid sequence does not share 99 percent identity over 66% of the length of a storage protein-encoding sequence obtained from *Triticum aestivum*, which SEQ ID NO: 11 does. Whether or not further research is required to find any specific or substantial utility for the sequence obtained from the BLASTN search (*i.e.*, the sequence obtained by Kawaura *et al.*) is not legally relevant to the determination of whether SEQ ID NO: 11 has a specific, substantial, or credible utility.

The utility of SEQ ID NO: 11 is further supported by a confirmatory BLASTN analysis. A confirmatory BLASTN analysis of SEQ ID NO: 11 demonstrates that the claimed nucleotide sequence shows 95 percent identity over 92% of the length of a storage-protein sequence obtained from *Triticum aestivum*.

```
>dbj|BJ310230.1|  BJ310230 Y. Ogihara unpublished cDNA library, Wh_yd
Triticum
aestivum cDNA clone whyd23f19 3', mRNA sequence.
Length=627
 Score =  580 bits (642),  Expect = 2e-162
 Identities = 347/362 (95%), Gaps = 2/362 (0%)
 Strand=Plus/Minus

Query  32   GAGCTCGACCC-GGACGGAATGGTGCAGGCGCTGGCCGCGGTGCTGCGGGACAAGATCAC  90
            |||||||||||  | |||||||||||||||||||||||| ||||||||||||||||||||
Sbjct  627  GAGCTCGACCCCGNACGGAATGGTGCAGGCGCTGGCCGCCGTGCTGCGGGACAAGATCAC  568
Query  91   CATGCCCGGCCAGCTCATGACCGACGGCCGCGACGCCGACTTGTTCGAGCACTTCTCGGC  150
            |||||||||||||||||||||||||||||||| |||||| |||| |||||||||||  ||
Sbjct  567  CATGCCCGGCCAGCTCATGACCGACGGCCGCGAGGCCGACCTGTTTGAGCACTTCTCAGC  508
Query  151  GGTCGCGCAGCGCACCGGGGTGTACACGGCAAGAGACTACGGCGACATGGTGGAGCACTT  210
            |||||||||||||||||||||||||||||||| |||||||||||||||||||||||||||
Sbjct  507  GGTCGCGCAGCGCACCGGGGTGTACACGGCAAGGGACTACGGCGACATGGTGGAGCACTT  448
Query  211  CGTGCGTAGGTGGAAGGTGGCGGACCTCGGCGGGGGGCAGCTGTCCGGGGAGGGGCGGCG  270
            ||||||  |||||||||||||  |||||||  |||||||||||||||||  |||||||  |||
Sbjct  447  CGTGCGGAGGTGGAAGGTGGCTGACCTCGCCGGGGGGCAGCTGTCCGGCGAGGGGC-GCG  389
Query  271  CGCGCAGGAGTACGTGTGCGGGCTGCCGCGCAAGATCCGGCGGGTGGAGGAGCTGGCCCA  330
            ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Sbjct  388  CGCGCAGGAGTACGTGTGCGGGCTGCCGCGCAAGATCCGGCGGGTGGAGGAGCTGGCCCA  329
Query  331  CGACCGCGTGATCAAAGCCGCAAAAGAGCCCGAGTTCGCAAGGTTCAGCTGGGTCTTCGA  390
            ||||||||  ||||||||||  ||||||||||||||||||||||||||||||||||||||
Sbjct  328  CGACCGCGCGATCAAAGCCGCGAAAGAGCCCGAGTTCGCAAGGTTCAGCTGGGTCTTCGA  269
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Query  391  CA  392
           ||
Sbjct  268  CA  267
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This sequence was obtained by Kawaura *et al.* and disclosed in the same reference (*Plant Physiol.* **139 (4)**, 1870–1880, 2005) recited in Applicants' Amendment of November 3, 2006. All information provided above is readily available from conducting the BLASTN analysis of SEQ ID NO: 11 through the National Center of Biotechnology Information (NCBI) website. The confirmatory BLASTN analysis provides additional support for Applicants' assertion that SEQ ID NO: 11 is reasonably correlated to a wheat storage protein-encoding sequence. A 95 percent identity over 92 percent of the length of a storage protein sequence obtained from *Triticum aestivum* is, without a doubt, a reasonable correlation.

In conclusion, Applicants respectfully submit that SEQ ID NO: 11 has specific, substantial, or credible utility because it has a reasonable correlation with a storage protein-encoding sequence obtained from *Triticum aestivum*, and can be used in a manner that provides some immediate benefit to the public. In other words, the claimed invention meets the utility test set forth in *In re Fisher*. Therefore, Applicants respectfully request that the Examiner reverse the rejection of claims 1 to 8 under 35 U.S.C. § 101.

III. Claim Rejections under 35 U.S.C. § 112, first paragraph (Enablement):

The Examiner rejected claims 1-4, 6, and 8 under 35 U.S.C. § 112, first paragraph, because, allegedly, since the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility, "one skilled in the art clearly would not know how to use the claimed invention". *Office Action* at page 7. Applicants respectfully disagree with the

rejection, and submit that this rejection has been overcome by the arguments set forth above with respect to the rejection under 35 U.S.C. § 101. In other words, Applicants respectfully submit that the claimed invention has specific, substantial, and credible utility and request that the Examiner reverse the rejection of claims 1 to 8 under the enablement requirement of 35 U.S.C. § 112, first paragraph.

IV. Claim Rejections under 35 U.S.C. § 112, first paragraph (Written Description):

The Examiner rejected claims 1-4, 6 and 8 under 35 U.S.C. § 112, first paragraph, as allegedly "not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention." *Office Action* at page 11. The Examiner admits that nucleic acids consisting of SEQ ID NO: 11 satisfy the written description requirements of 35 U.S.C. § 112, first paragraph. *Id.* at page 12. The Examiner further asserts, however, that "SEQ ID NO: 11 is an EST, and is less than a full length open reading frame," and accordingly Applicants have allegedly not adequately disclosed the claimed genera of nucleic acid molecules. *Id.* As such, the Examiner appears to require that each nucleic acid molecule within the claimed genera must be described by its complete structure. *Id.* This requirement is unfounded.

In particular, Applicants have disclosed common structural features of the genus of claimed nucleic acid molecules comprising the nucleotide sequence of SEQ ID NO: 11. For example, if a particular nucleic acid molecule contains the nucleotide sequence of SEQ ID NO: 11, then it is a member of the claimed genus of nucleic acid molecules comprising a nucleic acid sequence of SEQ ID NO: 11. Likewise, if a nucleic acid molecule comprises a nucleic acid

sequence that exhibits, for example, 93% identity to the nucleic acid sequence of SEQ ID NO: 11 or the complement thereof, then it also falls within the genus of nucleic acid molecules encompassed by claim 4, as amended.[1] Moreover, closely related nucleic acid molecules falling within the scope of the claimed invention are readily identifiable - they either contain the nucleic acid sequence of SEQ ID NO: 11, or share a claimed identity with SEQ ID NO: 11, or they do not. The fact that the nucleic acid molecules may comprise additional sequences or variations is beside the point. Such modifications are readily envisioned by one of ordinary skill in the art and disclosed throughout the specification. Thus, contrary to the Examiner's analysis, claims 1-4, 6, and 8 are supported by an adequate written description pursuant to the requirements of 35 U.S.C. § 112, and the rejection should be reversed.

The Examiner's position, however, is that "the specification does not disclose what specific sequence information must be shared by the claimed genus of nucleic acid molecules in order to ascertain which nucleic acids share a common structural feature." *Id* at page 18. This analysis misses the point of the written description requirement. The purpose of the written description requirement is to ensure that the inventor had possession of the claimed subject matter, *i.e.*, to ensure that the inventors actually invented what is claimed. *Gentry Gallery Inc. v. Berkline Corp.*, 134 F.3d 1473, 1479 (Fed. Cir. 1998); *Lockwood v. American Airlines*, 107 F.3d 1565, 1572 (Fed. Cir. 1997); *In re Alton*, 76 F.3d 1168, 1172 (Fed. Cir. 1996). In accordance with this purpose, Applicants need not "describe," in the sense of 35 U.S.C. § 112, all things that

[1] The same argument applies with equal force to every genus of the claimed nucleic acid molecules. For example, if a nucleic acid molecule contains a nucleic acid sequence that has 95% identity with the entire length of SEQ ID NO: 11, then it is a member of the claimed genus of nucleic acid molecules having between 95% and 100% identity with the entire length of SEQ ID NO: 11. *See* new claim 9.

are encompassed by the claims. To contend otherwise would contradict established jurisprudence, which teaches that a patent may be infringed by technology developed after a patent issues. *United States Steel Corp. v. Phillips Petroleum Co.*, 865 F.2d 1247, 1251 (Fed. Cir. 1989). A related, and equally well-established principle of patent law is that claims "may be broader than the specific embodiment disclosed in a specification." *Ralston-Purina Co. v. Far-mor-Co*, 772 F.2d 1570, 1575 (Fed. Cir. 1985), *quoting In re Rasmussen*, 650 F.2d 1212, 1215 (C.C.P.A. 1981). Thus, in order for Applicants to describe each and every molecule encompassed by the claims, it is not required that every aspect of those nucleic acid molecules be disclosed. *In re Alton*, 76 F.3d at 1175 (if a person of ordinary skill in the art would, after reading the specification, understand that the inventors had possession of the claimed invention, even if not every nuance, then the written description has been met).

An adequate written description of a genus of nucleic acids, such as those recited in claims 1-4, 6, and 8, may be achieved by either "a recitation of a representative number of [nucleic acid molecules], defined by nucleotide sequence, falling within the scope of genus or of a recitation of structural features common to the members of the genus." *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559, 1568-69 (Fed. Cir. 1997). The feature relied upon to describe the claimed genus must be capable of distinguishing members of the claimed genus from non-members. *Id.* Further, Applicants need not describe every possible sequence that may be included in the claimed genus of nucleic acid molecules. Indeed, recently, the Federal Circuit stated that "[i]t is not necessary that every permutation within a generally operable invention be effective in order for an inventor to obtain a generic claim, provided that

the effect is sufficiently demonstrated to characterize a generic invention." *Capon v. Eshhar*, 418 F.3d 1349, 1359 (Fed. Cir. 2005). Applicants have satisfied this requirement.

The Examiner argues that it is not clear that SEQ ID NO: 11 encodes a protein. *Office Action* at page 13. This position misses the point of the written description requirement. It is well-established law that use of the transitional term "comprising" properly leaves the claims "open for the inclusion of unspecified ingredients even in major amounts." *Ex parte Davis*, 80 U.S.P.Q. 448, 450 (B.P.A.I. 1948). *Accord PPG Indus. v. Guardian Indus.*, 156 F.3d 1351, 1354 (Fed. Cir. 1998); *Moleculon Research Corp. v. CBS*, 793 F.2d 1261, 1271 (Fed. Cir. 1986). Nucleic acid molecules falling within the scope of claim 2, for example, are readily identifiable and one of ordinary skill in the art can readily identify whether a particular sequence meets the claimed characteristics or not. The fact that the nucleic acid molecules may comprise additional sequences or variations is beside the point. Such modifications are readily envisioned by one of ordinary skill in the art and disclosed throughout the specification. *See, for example, Specification* at page 17, line 27, to page 18, line 8 (describing gene sequences and corresponding sequences from other species); at page 19, line 14, to page 21, line 22 (describing conservative amino acid substitutions); at page 22, line 8, to page 23, line 13 (describing SNPs); at page 49, lines 9 to 30 (describing site-directed mutagenesis); and at page 53, line 3, to page 54, line 11 (describing various vectors including the claimed nucleic acid molecules). The fact that the claims at issue are intended to cover molecules that include the recited sequence joined with additional sequences, or complements of the recited sequence, does not mean that Applicants were any less in possession of the claimed nucleic acid molecules. In light of the disclosure of

the specification, it would be readily ascertainable to one of skill in the art which of the claimed nucleic acid molecules encode a wheat protein or fragment thereof.

The Examiner further argues that the "genus of nucleic acids claimed is large and variable..." *Id.* at page 19. Such an assertion is not a proper basis to reject the pending claims under 35 U.S.C. § 112. *See, e.g., Johnson Worldwide Assoc., Inc. V. Zebco Corp.*, 175 F. 3d 985, 993 (Fed. Cir. 1999) (holding the patent disclosure "provide[d] ample support for the breadth of the term 'heading' " to satisfy the written description requirement.) As previously stated, all Applicants must do in this case to satisfy the written description requirement under the test set forth in *Eli Lilly and Co.* is to provide a common structural feature of the claimed nucleic acid molecules that distinguishes members of the claimed genus of nucleic acid molecules from non-members of the claimed genus. *Eli Lilly and Co.*, 119 F.3d at 1568-69. Applicants have met that burden here.

The Examiner has offered no evidence to demonstrate why one of ordinary skill in the art would reasonably doubt that Applicants have adequately described the claimed invention in the present disclosure. The claimed genus of nucleic acids share the common structural feature of containing the sequence of SEQ ID NO: 11. Even the Examiner admits that while the specification is not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. *Office Action* at page 17. Whether or not the genus is large or variable, it shares a common structural feature, *i.e.*, the sequence of SEQ ID NO: 11, and one of ordinary skill in the art would recognize that Applicants were in possession of the claimed genus of nucleic acid molecules.

The fundamental factual inquiry for satisfying the written description requirement is whether the specification conveys with reasonable clarity to those skilled in the art, as of the filing date sought, that Applicants were in possession of the invention as now claimed. *See, e.g., Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64 (Fed. Cir. 1991). An Applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations. *Lockwood*, 107 F.3d at 1572; M.P.E.P. § 2163.02. In light of the disclosure of the specification one of ordinary skill in the art at the time the application was filed would have readily recognized that Applicants were in possession of the invention as claimed. By describing the common structural feature of the claimed nucleic acid molecules, *i.e.,* SEQ ID NO: 11, Applicants respectfully submit that they have satisfied, at least, the Eli Lilly test for written description. Therefore, Applicants respectfully request that the Examiner reverse the rejection of claims 1-4, 6, and 8 under 35 U.S.C. § 112, first paragraph.

V. Claim Rejections under 35 U.S.C. § 102:

a) EST accession number AW566142

Claims 1 and 4 were rejected under 35 U.S.C. § 102(a) as allegedly "being anticipated by EST accession number AW566142." *Office Action* at page 20. Applicants respectfully disagree with this rejection.

"It is axiomatic that for prior art to anticipate under § 102 it has to meet every element of the claimed invention. *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1369, 231 U.S.P.Q. 81, 90 (Fed. Cir. 1986). Further, "an anticipation rejection requires a showing that each limitation of a claim must be found in a single reference, practice, or device." *In re Donohue*, 766 F.2d 531, 534, 226 U.S.P.Q. 619, 621 (Fed. Cir. 1985). The Examiner has applied an

untenable interpretation of the claims to cover sequences that encompass any fragment of SEQ ID NO: 11, and thus concludes that the claims are anticipated. Applicants have amended claims 1 and 4 to assist the Examiner, rendering the issue moot.

Moreover, the sequence provided by EST accession number AW566142 exhibits only 78% identity with the entire length of SEQ ID NO: 11. Whatever else EST accession number AW566142, it does not disclose a substantially purified nucleic acid molecule comprising the nucleotide sequence of SEQ ID NO: 11 or the complement thereof, nor does it disclose a nucleotide sequence that shares between 90% and 100% sequence identity with the entire length of SEQ ID NO: 11 or the complement thereof, as recited in amended claims 1 and 4. Absent a teaching of each and every element of the claims, EST accession number AW566142 cannot anticipate claims 1 and 4.

The Applicants remind the Examiner that during examination, the "claims must be given their broadest reasonable interpretation", M.P.E.P. § 2111 (emphasis added), and this interpretation must be consistent with the interpretation that those skilled in the art would reach. *In re Cortright*, 165 F.3d 1353, 1359, 49 USPQ2d 1464, 1468 (Fed. Cir. 1999). One of ordinary skill in the art would not reasonably interpret a nucleic acid sequence of SEQ ID NO: 11 as encompassing any fragment of SEQ ID NO: 11. Thus, Applicants respectfully request withdrawal of this rejection.

b) EST accession number AI677542

Claims 1 and 4 were also rejected under 35 U.S.C. § 102(a) as allegedly "being anticipated by EST accession number AI677542." *Office Action* at page 21. As indicated above with respect to EST accession number AW566142, one of ordinary skill in the art would not

consider a fragment of SEQ ID NO: 11 to be identical to SEQ ID NO: 11 or its complement, both of which are 392 bases in length. The Examiner has applied an untenable interpretation of the pending claims to cover small fragments of the specifically claimed nucleic acid molecules, and thus concludes that the claims are anticipated by the cited reference. Such an interpretation would be unreasonable and Applicants respectfully submit that EST accession number AI677542 does not anticipate claims 1 and 4, as amended, for the reasons discussed above. The sequence provided by EST accession number AI677542 exhibits only 66% identity with the entire length of SEQ ID NO: 11. Applicants have amended claims 1 and 4 to assist the Examiner, rendering the issue moot. Therefore, based on the foregoing, Applicants respectfully request reconsideration and withdrawal of this rejection.

c) Cahoon *et al.*

Claims 1 and 4 were also rejected under 35 U.S.C. § 102(e) as allegedly "being anticipated by Cahoon *et al.*." *Office Action* at page 23. As indicated above with respect to EST accession number AW566142, one of ordinary skill in the art would not consider a fragment of SEQ ID NO: 11 to be identical to SEQ ID NO: 11 or its complement, both of which are 392 bases in length. The Examiner has applied an untenable interpretation of the pending claims to cover small fragments of the specifically claimed nucleic acid molecules, and thus concludes that the claims are anticipated by the cited reference. Such an interpretation would be unreasonable, therefore, Applicants respectfully submit that the nucleic acid molecule taught by Cahoon *et al.* does not anticipate claims 1 and 4 as amended. The sequence provided by Cahoon *et al.* exhibits only 60% identity with the entire length of SEQ ID NO: 11. Nonetheless, Applicants have

amended claims 1 and 4 to assist the Examiner, rendering the issue moot. Therefore, the Applicants respectfully request reconsideration and withdrawal of this rejection.

d) Genbank Accession Number AF020203

Claims 1 and 4 were also rejected under 35 U.S.C. § 102(b) as allegedly "being anticipated by Genbank Accession Number AF020203 (1998)." *Office Action* at page 24. Applicants have amended claims 1 and 4 to assist the Examiner, rendering the issue moot. Moreover, as indicated above with respect to EST accession number AW566142, one of ordinary skill in the art would not consider a fragment of SEQ ID NO: 11 to be identical to SEQ ID NO: 11 or its complement, both of which are 392 bases in length. The Examiner has applied an untenable interpretation of the pending claims to cover small fragments of the specifically claimed nucleic acid molecules, and thus concludes that the claims are anticipated by the cited reference. Such an interpretation would be unreasonable and Applicants respectfully submit that the nucleic acid molecule taught by Genbank Accession Number AF020203 does not anticipate claims 1 and 4 as amended for the reasons discussed above with respect to the rejections over EST accession numbers AW566142, and AI677542, and Cahoon *et al.* The sequence provided by Genbank Accession Number AF020203 exhibits only 64% identity with the entire length of SEQ ID NO: 11. Therefore, based on the foregoing, Applicants respectfully request reconsideration and withdrawal of this rejection.

e) NEB Catalog

Claims 1, 2, 4, and 5 were also rejected under 35 U.S.C. § 102(b) as allegedly "being anticipated by NEB Catalog (1998/1999)." *Office Action* at page 25. For the reasons indicated above with respect to EST accession numbers AW566142, AI677542 and AF020203, and

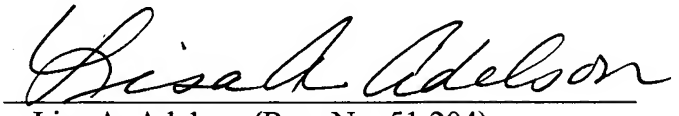
Cahoon *et al.*, one of ordinary skill in the art would not consider a fragment of SEQ ID NO: 11 to be identical to SEQ ID NO: 11 or its complement, both of which are 392 bases in length. Applicants have amended pending claims 1 and 4 to assist the Examiner, rendering the issue moot. Moreover, the Examiner has applied an untenable interpretation of the pending claims to cover small fragments of the specifically claimed nucleic acid molecules, *i.e.*, fragments as short as 12 nucleotides and 24 nucleotides, and thus concludes that the claims are anticipated by the cited reference. Such an interpretation would be unreasonable and the Applicants respectfully submit that the nucleic acid molecules taught by NEB Catalog do not anticipate pending claims 1, 2 and 4. Therefore, the Applicants respectfully request reconsideration and withdrawal of this rejection.

CONCLUSION

In view of the foregoing amendments and remarks, the Applicants respectfully submit that the present application is now in condition for allowance, and respectfully request notice of such. The Examiner is encouraged to contact the undersigned at 202-942-5325 if any additional information is necessary for allowance.

Respectfully submitted,

Date: February 21, 2008



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